American Latex Allergy Association

Anaphylaxis

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Enhancing Patient Safety

When it comes to anaphylaxis, every second counts, so knowing how to properly use the EpiPen Auto-Injector is key. Because Dey Pharmaceuticals is conscious of this and committed to making quality improvements, the company is happy to introduce the new ?Patient First? packaging and labeling for all EpiPen and EpiPen Jr. Auto-Injectors in June 2005.

The new packaging negates the need for patients to carry instructions. The three steps to properly using EpiPen are outlined in words and pictures on the side of the injector ? so using an EpiPen is now as easy as 1, 2, 3.

Patients can just look at the side of their injectors when they need to use their EpiPen and they are guided to remove the safety release cap, inject the epinephrine and seek medical attention.

Additionally, the carrying case has been redesigned with distinctive color-coded caps and labeling-yellow for EpiPen and green for EpiPen Jr. The new case also provides built-in needle protection for safe storage of used Auto-Injectors. Each 2-Pak comes with a convenient S-clip, making it easier to carry both doses at the same time.

For more information, contact Dey at 1-800-755-5560 or visit **www.epipen.com** [1].

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A Definition of Anaphylaxis

Anaphylaxis, or anaphylactic shock, is a systemic allergic reaction that can kill within minutes, either through swelling that shuts off airways or through a fatal drop in blood pressure. Anaphylaxis occurs in allergic individuals when they are exposed to the protein/allergen to which they are allergic. Contact with or ingestion of this allergen will set off a chain reaction that may lead to swelling of the airways, loss of blood pressure and loss of consciousness, sending them into anaphylactic shock. Some anaphylactic reactions involve only one organ

system, such as the respiratory tract; however, it is possible for anaphylaxis to affect multiple systems simultaneously, including the upper and lower respiratory tracts, cardiovascular system and gastrointestinal tract. In essence, the immune systems of allergic individuals perceive the allergen (insect venom, food proteins, latex rubber, medications) as a threatening foreign substance and their bodies are primed or sensitized to react against it. More specifically, the part of the immune system that is usually involved in fighting parasites forms proteins called IgE antibodies that sit on the surface of allergy or mast cells. These cells are filled with chemicals such as histamine and leukotriene that are released when the allergenic protein reacts with the IgE. The release of these IgE mediators causes smooth muscle contraction, which can produce wheezing and gastrointestinal symptoms, and vascular dilation that in turn can cause swelling (angioedema), hives (urticaria) and a decrease in plasma volume that can lead to shock.

For the majority of severe allergy sufferers, avoidance of the specific allergens that trigger their reactions and being prepared to treat those that occur with an immediate shot of epinephrine are their only options. According to the American Academy of Allergy, Asthma and Immunology, people who have experienced symptoms of anaphylaxis previously are at risk for subsequent reactions and should carry an epinephrine injector with them at all times. EpiPen® offers a pre-measured dose of epinephrine for self-administration that is simple to use (a push-activated, automatic injection) and is easily carried in a pocket or purse. Moreover, it is safe for latex-allergic patients because, unlike many syringes or IV tubes, EpiPen contains no latex. Side effects of EpiPen may include fast or irregular heartbeat, nausea, and breathing difficulty. Please visit **www.epipen.com** [1] for full prescribing information.

In addition to carrying epinephrine with them, people with life-threatening allergies should also make sure that injectors are readily available in their home, office, school or anywhere else they spend a lot of time. Parents of children with life-threatening allergies should make sure that their children?s teachers and caregivers have an epinephrine auto-injector on hand and know how to administer it.

Additionally, patients should ask their physicians whether antihistamines should be carried in addition to epinephrine. And wearing a medical identification bracelet indicating the patient?s allergies and susceptibility to anaphylaxis can help ensure prompt, proper treatment during an emergency.

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Being Prepared for an Anaphylactic Emergency

As with other potentially life-threatening allergies, the primary method of protection is avoiding contact with what causes the reactions and being prepared to treat anaphylactic emergencies with epinephrine injections and prompt medical attention.

Avoidance - Avoidance is crucial in guarding against further sensitization and severe allergic reactions to latex. People who exhibit allergic symptoms after contact with latex should substitute latex-free versions of latex products in their home and workplace, and should alert their healthcare practitioners that they need to be treated with latex-free equipment.

Though latex seems to be everywhere and is difficult to avoid entirely, avoidance is becoming easier as healthcare facilities, professional organizations, consumer advocacy groups, policy makers and even manufacturers are working to make latex substitutes or at least powder-free, low-protein latex products more

readily available. Latex-free trays, examining and operating rooms, dental and emergency equipment are becoming more standard. Vinyl gloves are available, if expensive, and manufacturers are working on better, more affordable synthetic substitutes.

Emergency Treatment - Because not all allergic reactions can be avoided, and because allergic reactions can progress quickly to deadly anaphylaxis, the American Academy of Allergy, Asthma & Immunology suggests that people allergic to latex consult their doctors about carrying a form of self-injectable epinephrine such as EpiPen® auto-injectors and administering it at the first sign of a severe allergic reaction.

Epinephrine, or adrenaline, works rapidly to reverse the symptoms of anaphylaxis by relaxing smooth muscle tissue in the lungs, speeding up the heart rate, combating hives and welts on the skin, and reducing the swelling of the mouth, throat, and face.

Side effects of epinephrine may include palpitations, tachycardia (an abnormally fast heartbeat), sweating, nausea and vomiting, and respiratory difficulty. Cardiac arrhythmias may follow administration of epinephrine. Patients should be carefully instructed by a physician about the circumstances under which this life-saving medication should be used.

Many physicians also recommend that antihistamines such as diphenhydramine be administered to lessen the symptoms of an allergic reaction, but antihistamines should only be taken in addition to epinephrine for the treatment of anaphylaxis and should not be considered a substitute for it. Only epinephrine can halt the potentially deadly effects of anaphylaxis.

Even after administering epinephrine, emergency medical treatment should be sought at once because severely allergic people experiencing anaphylaxis may need emergency respiratory or cardiac care, or even to be resuscitated if they stop breathing altogether. More commonly, these patients will need professional care to determine whether additional epinephrine, steroids, antihistamines, or other treatments are required. Either way, follow-up diagnosis and care by medical professionals after administration of epinephrine is critical to recovery. Delayed or secondary reactions do occur, and patients should remain under medical supervision for at least four hours after an episode of anaphylaxis occurs.

Additionally, wearing a medical identification bracelet describing the patient?s allergies and susceptibility to anaphylaxis can help ensure prompt, proper treatment during an emergency.

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EpiPen Facts

What is an EpiPen?

EpiPen is a self-administered auto-injector that delivers a pre-measured single dose of epinephrine, also known as adrenaline, by means of a concealed, spring-loaded needle. EpiPen is indicated for the emergency treatment of severe life-threatening allergic reactions known as anaphylaxis.

How is EpiPen administered?

EpiPen only takes a few seconds to administer since speed is critical in an anaphylactic emergency. Patients are directed to remove the gray activation cap, make a fist around the unit and quickly swing and jab the black tip into the outer part of the thigh. Patients must be sure to hold the EpiPen in place for 5-10 seconds to be sure the full dose of epinephrine is received. Epinephrine is automatically injected into the muscle, which is the fastest way to deliver the drug into the bloodstream. EpiPen can work through clothes, even heavy materials such as the denim used for jeans. How does EpiPen treat the symptoms of anaphylaxis? Epinephrine, the key ingredient in an EpiPen, helps halt the potentially fatal symptoms of anaphylaxis and creates a window of time for patients to reach emergency medical care. Specifically, epinephrine constricts blood vessels, relaxes smooth muscles in the lungs to improve breathing, stimulates the heart beat, and works to reverse hives and swelling around the face and lips (angioedema). The effects of one dose of epinephrine usually last 10 to 20 minutes. Administration of EpiPen should always be followed by emergency room care.

Who should carry an EpiPen?

The American Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI) recommend that people with life-threatening allergies carry an injectable form of epinephrine (adrenaline) such as an EpiPen auto-injector with them at all times. The most common triggers of severe allergic reactions include food, medicine, insect venom, latex and, in rare cases, exercise.

What are the key patient benefits of having an EpiPen?

Tailored dosing ? EpiPen comes in two dosages: 0.3 mg EpiPen for adults and children weighing more than 66 lbs. (30 kg), and 0.15 mg EpiPen® Jr. for children weighing between 33 and 66 lbs. EpiPen Jr. ensures the proper dosing for smaller children with severe allergies.
EpiPen® 2-Pak™ - EpiPen and EpiPen Jr. 2-Paks offer individuals suffering from severe allergies the advantage of being able to obtain two auto-injectors and a trainer in one package, with one prescription.

A trainer - The trainer is a reusable, needle-free training device that simulates the action of an EpiPen. Patients can use it to practice on themselves and teach family and friends how to administer the auto-injector in case of an emergency. Multiple units for flexibility, extra insurance ? EpiPen 2-Pak offers patients the added protection of multiple units. Patients can leave units in several locations for immediate access in the event of an emergency. In addition, some patients may need more than one dose to reverse the symptoms of an especially severe reaction or to allow enough time to reach professional medical care should they be more than 15 minutes from a hospital. Two auto-injectors for fumble-free administration ? Patients can be confident that a second dose will be administered correctly because it is auto-injectable, instead of requiring a manual injection.

Latex free - Unlike many medical devices, EpiPen contains no latex, a common anaphylaxis trigger. EpiPen Patient Relationship Program - Patients are invited to enroll in this free program to receive reminders one month before their unit is about to expire. This unique program helps patients make sure that their EpiPen units are always current and ready to use in an emergency. For more information on this program, visit the web site **www.EpiPen.com** [2]. Thousands of patients trust EpiPen - EpiPen is the leading prescription product and the preferred choice of physicians and patients because it is the fastest, easiest self-administered epinephrine that can be prescribed. On the market since 1980, doctors in the United States have written more than 4.7 million prescriptions for EpiPen in the last 4 years alone (1998-2002).

Are there any side effects associated with EpiPen?

EpiPen is available by prescription only. EpiPen should be used with extreme caution in people who have heart disease. Side effects of EpiPen may include fast or irregular heartbeat, nausea, and difficulty breathing. These may increase if you are taking tricyclic antidepressants or MAOIs. For more information about EpiPen, please visit the web site **www.EpiPen.com** [3]. (pdf)

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American Latex Allergy Association

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Website: www.latexallergyresources.org

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